norm

SECTION 2

510 (k) SUMMARY

OCT 2 8 2009

2.1 OWNER / SUBMITTER INFORMATION:

Owner: Norm Tıbbi Ürünler İthalat İhracat Sanayi ve Ticaret Limited Şirketi
Address: 1. Cad. No: 5/1 Balgat / Ankara Turkey
Phone Number: +90 312 2840080
Fax Number: +90 312 2853093
Contact Person: Nuray Doğan
Date Prepared: 01 July 2009

2.2 DEVICE INFORMATION:

Common or Usual Name:	Spinal Fixation System
Proposed Proprietary or Trade Name:	Norm Spinal System
Classification Name:	Spondylolisthesis Spinal Fixation Device System and Pedicle Screw System (per 21 CFR 888.3070)
Product Codes:	MNH, MNI

2.3 SUBSTANTIAL EQUIVALENCE:

Norm Spinal System is substantially equivalent to the legally marketed in function, intended use, material and design to
4S Spinal System (K063708) and Optima Spinal System (K031585).

2.4 DEVICE DESCRIPTION:

Norm Spinal System is a top-loading multiple component, posterior spinal fixation system consisting of polyaxial pedicle screws, rods and set screw. The Norm Spinal System will allow surgeons to build a spinal implant construction to stabilize and promote spinal fusion and it functions to build a spinal implant construct to stabilize and promote spinal fusion. The Norm Spinal System components are supplied non-sterile, single use and fabricated from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136. Various sizes of these components are available.

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1. Cadde No: 5/1 Balgat Çankaya / ANKARA Tel: 0 312 284 00 80 - 284 83 88 • Faks: 0 312 285 30 93 • www.normltd.net

2.5 INDICATION OF USE:

NORM spinal system implants are designed to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following indications of the thoracic lumbar and sacral spine:

- degenerative spondylolisthesis with objective evidence of neurological impairment;
- fracture;
- dislocation;
- scoliosis;
- kyphosis;
- spinal tumor; and failed previous fusion (pseudarthrosis).

Levels of fixation are for the thoracic, lumbar and sacral spine.

Norm Posterior Spinal System is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogeneous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attachment of a solid fusion.

2.6 STATEMENT OF TECHNICAL COMPARISON:

The summary of the technological characteristics of the Norm Spinal System compared to the predicate devices are as follows:

2.6.1 Material

The Norm Spinal System and predicate devices are fabricated by the same material that is titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136.

2.6.2 Design

The Norm Spinal System and predicate devices have similar designed and sized components which are polyaxial screws, cylindrical longitudinal rods and set screws. Also, the Norm Spinal System and predicate devices have similar top-loading interconnection mechanism.

2.6.3 Function

The Norm Posterior Spinal System and predicate devices have similar functions which are acting as a spinal implant construct to stabilize and promote spinal fusion.

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2.6.4 Level of Attachment

Levels of fixation of the Norm Posterior Spinal System are for the thoracic, lumbar and sacral spine. Similarly predicate devices are also intended to attach to spinal segment of thoracic, lumbar and sacral.

2.6.5 Intended Use

The Norm Posterior Spinal System is indicated for the same intended uses as the predicate devices.

2.6.6 Sterility

The Norm Posterior Spinal System is supplied in non-sterile and single use. Similarly the predicate devices are supplied non-sterile and single use.

2.7 NON-CLINICAL PERFORMANCE TESTING:

Non-clinical testing including static compressive, static torsion and dynamic compressive tests according to ASTM F 1798-97, ASTM F 543-02, ASTM F 2193-02 and ASTM F 1717-04 has been conducted and the test results may be seen in Appendix 6. The result of these mechanical tests demonstrates that the Norm Spinal System is as safe, as effective, and performs as well as or better than the predicate devices and equivalent to the above predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Norm Tibbi Urunler Ithalat Ihracat Sanayi Ve Ticar LTD.
% Mr. Nuray Dogan
Director of Import Department
1Cadde No:5/1 Balgat
Ankara, Turkey 06520

OCT 2 8 2009

Re: K092011
Trade/Device Name: Norm Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNH, MNI
Dated: October 14, 2009
Received: October 19, 2009

Dear Mr. Dugan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092011

Device Name: Norm Spinal System

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092011